K062384

510(k) Summary of Safety and Effectiveness

NOV - 9 2006

Summary Date: August 14, 2006

Submitter Information: IsoRay Medical, Inc.
350 Hills Street, Suite 106
Richland, WA 99354
Phone: 509-375-1202
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Contact Person: David J. Swanberg, Executive Vice President of Operations

Email: dswanberg@isoray.com

Trade Name: Cesium-131 Implant Devices, Multiple

A) Cesium-131 Strand, Model PL-1
B) Cesium-131 Strand Preload, Model PL-2
C) Cesium-131 Preload, Model PL-3
D) Cesium-131 S-Cartridge, Model PL-4

Common Name: Custom Preload Devices

A) Stranded Seeds
B) Stranded Seeds Preloaded in Needles
C) Loose Seeds Preloaded in Needles
D) Seeds in Sterile Cartridges

Primary Predicate Devices:

1) K030162 Cs-131 Brachytherapy Seed, Model CS-1
2) K011155 Interstrand^{125} and Interstrand^{103}
3) K030594 I-125 Rapid Strand, Model 7000
4) K043336 Optistrand, Model 1032S
5) K040339 Brachytherapy Strand Device
6) K041702 EZ-Pak
7) K043596 Theraload Custom Loaded Needles, Models 200 & 1
8) K060636 Palladium-103 Seed Implant Preloads – Multiple

Device Descriptions: The IsoRay Medical, Inc. Cesium-131 Strand, Model PL-1, contains absorbable seeding spacers and Cs-131 Brachytherapy Seeds enclosed in a bio-absorbable brachytherapy sleeve and sterilized using ethylene oxide. The seeds and spacers are arranged according to a treatment plan provided by a physician or medical physicist.

For the IsoRay Medical, Inc. Cesium-131 Strand Preload, Model PL-2, each Cesium-131 Strand, Model PL-1, is placed in a brachytherapy needle which is pre-plugged with bone wax to hold the strand in position. The arrangement of the seeds and spacers and the strands in the needles is dictated by the treatment plan. The strands are sterilized after loading into needles using ethylene oxide.

The IsoRay Medical, Inc. Cesium-131 Preload, Model PL-3, contains absorbable seeding spacers and Cs-131 Brachytherapy Seeds within a brachytherapy needle which is pre-plugged with bone wax to keep the seeds and spacers in position. The arrangement of the seeds and spacers in each needle is dictated by the treatment plan. The preloaded needles are then sterilized using ethylene oxide.

The IsoRay Medical, Inc. Cesium-131 S-Cartridge, Model PL-4 contains Cs-131 Brachytherapy Seeds, loaded into Mick® cartridges and sterilized by either steam or ethylene oxide.

Note: The above-listed devices may be assembled using components with equivalent composition and function that are FDA-cleared for the same intended use or otherwise determined to be exempt or pre-amendment devices.

Packaging: The above-listed devices are supplied in packaging material that has met formal, documented qualifications and validation programs for terminally sterilized medical devices. The packaging also meets Department of Transportation performance test requirements for Type 7A (radioactive material) packaging.

Indications for Use: The IsoRay Medical, Inc. Cesium-131 Implant Devices are indicated for the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.), and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. These devices may be used as a primary treatment or in conjunction with other treatment modalities, such as external beam radiation therapy, chemotherapy or as treatment for residual disease after excision of primary tumors.

The Cesium-131 Implant Devices have the same indications for use as the original device, the IsoRay Medical, Inc. Cs-131 Brachytherapy Seed, Model CS-1.

Substantial Equivalence

The IsoRay Medical, Inc. Cesium-131 Implant Devices are developed and manufactured with the same science and technology as the IsoRay Medical, Inc. Cs-131 Brachytherapy Seed. The Implant Devices also have multiple similarities to the other predicate devices, including:

1. All are sterile
2. All of the materials that contact the patient are biocompatible
3. All of the brachytherapy sources contain a radiopaque marker material to allow imaging the sources using Computerized Axial Tomography (CT), fluoroscopy or other X-ray techniques
4. All are low energy x-ray emitting brachytherapy sources
5. All of the brachytherapy sources have short half-lives

All the devices, as mentioned above, have a radiopaque marker. This marker is used to determine the exact location of the implanted sources and assist in the calculation of the therapeutic radiation dose pattern. The materials used for the radiopaque markers vary. The most common type of markers used are gold or gold alloy, silver, platinum, or a platinum/iridium combination. Regardless of the material selected for the radiopaque marker, there is no effect on the intended use of the marker, which is the determination of seed location primarily for dose calculations.

There are three primary isotopes compared in this document: Cesium-131, Palladium-103 and Iodine-125. Although these isotopes are different, they all provide therapeutic doses of radiation to the patient as dictated by the treatment plan provided by the physician or medical physicist.

Based on the information provided within this document, we conclude that the IsoRay Medical, Inc. Cesium-131 Implant Devices are substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. David Swanberg, P.E.
Executive Vice President of Operations
IsoRay Medical, Inc.
350 Hills St., Ste. 106
RICHLAND WA 99354-5411

NOV - 9 2006

Re: K062384
Trade/Device Name: Cesium-131 Implant Devices, Multiple
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: October 9, 2006
Received: October 10, 2006

Dear Mr. Swanberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): submitted K062384

Device Name: Cesium-131 Implant Devices, Multiple

Indications For Use: (Page 1 of 1)

IsoRay Medical, Inc. Cesium-131 Implant Devices are indicated for the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.) and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. These devices may be used as a primary treatment or in conjunction with other treatment modalities, such as external beam radiation therapy, chemotherapy or as treatment for residual disease after excision of primary tumors.

The Cesium-131 Implant Devices have the same indications for use as the original device, the IsoRay Medical Inc. Cs-131 Brachytherapy Seed, Model CS-1

Prescription Use X (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062384